Please amend the subject application as follows.

IN THE CLAIMS:

Please amend claims 1, 2, 5, 9, 10, 11, 14, 16, 20, and 21 and add new claim 24 as follows:

Claim 1 (Currently Amended). A method for assessing therapeutic effectiveness of a treatment agent for renal disease and/or renal complications of a disease, comprising:

(a) administering a treatment agent to a patient;

(b) obtaining a urine sample ~~of body fluid~~ from the patient;

(c) assaying for a protein in the urine sample by detecting the native form of the protein and intact modified form of the protein in the urine sample, wherein presence of or lack of the native and/or intact modified form of the protein in the urine sample or decreasing amount of the protein over time in the urine correlates with effectiveness of the treatment agent.

B' cont'd.

Claim 2 (Currently Amended). The method according to claim 1, wherein the renal disease and/or renal complications of the disease is selected from the group consisting of nephropathy, diabetes insipidus, diabetes type I, diabetes II, renal disease, glomerulonephritis, bacterial glomerulonephritis, ~~and~~ viral ~~glomerulonephritides~~ glomerulonephritis, IgA nephropathy, ~~and~~ Henoch-Schönlein Purpura, membranoproliferative glomerulonephritis, membranous nephropathy, Sjögren's syndrome, nephrotic syndrome, ~~(~~minimal change disease, focal glomerulosclerosis ~~and related disorders)~~, acute renal failure, acute tubulointerstitial nephritis, pyelonephritis, GU tract inflammatory disease, Pre-clampsia, renal graft rejection, leprosy, reflux nephropathy, nephrolithiasis~~)~~, genetic renal disease, ~~(~~medullary cystic, medullar sponge, polycystic kidney

disease, ~~(~~autosomal dominant polycystic kidney disease, autosomal recessive polycystic kidney disease, tuborous sclerosis~~)~~, von Hippel-Lindau disease, familial thin-glomerular basement membrane disease, collagen III glomerulopathy, fibronectin glomerulopathy, Alport's syndrome, Fabry's disease, Nail-Patella Syndrome, congenital urologic anomalies~~)~~, monoclonal gammopathies, ~~(~~multiple myeloma, amyloidosis ~~and related disorders)~~, febrile illness, ~~(~~familial Mediterranean fever, HIV infection -AIDS~~)~~, inflammatory disease, ~~(~~systemic vasculitides, ~~(~~polyarteritis nodosa, Wegener's granulomatosis, polyarteritis, necrotizing, ~~and~~ crescentic glomerulonephritis~~)~~, polymyositis-dermatomyositis, pancreatitis, rheumatoid arthritis, systemic lupus erythematosus, gout), blood disorders, ~~(~~sickle cell disease, thrombotic thrombocytopenia purpura, hemolytic-uremic syndrome, acute corticol necrosis, renal thromboembolism~~)~~, trauma, ~~and~~ surgery, ~~(~~extensive injury, burns, abdominal and vascular surgery, induction of anesthesia~~)~~, drugs ~~(penicillamine, steroids)~~, ~~and~~ drug abuse, malignant disease ~~epithelial (lung, breast)~~, adenocarcinoma ~~(renal)~~, melanoma, lymphoreticular, multiple myeloma~~)~~, circulatory disease, ~~(~~myocardial infarction, cardiac failure, peripheral vascular disease, hypertension, coronary heart disease, non-atherosclerotic cardiovascular disease, atherosclerotic cardiovascular disease~~)~~, skin disease, ~~(~~psoriasis, systemic sclerosis~~)~~, respiratory disease, ~~(~~COPD, obstructive sleep apnoea, hypoia at high altitude~~)~~, ~~and~~ endocrine disease, ~~(~~acromegaly, diabetes mellitus, and diabetes insipidus~~)~~.

Claim 3 (Original). The method according to claim 1, wherein the treatment agent is a lysosome-activating compound.

Claim 4 (Original). The method according to claim 3, wherein the lysosome-activating compound is selected from the group consisting of ACE

inhibitors, anti-glycation agents, anticancer compounds, antiproliferation compounds, and compounds that neutralize TGF-beta.

Claim 5 (Currently Amended). The method according to claim 3, wherein the lysosome-activating compound is selected from the group consisting of ramipril, aminoguanidine, paracetamol, vitamin A, ~~(retinoic acid)~~, retinol derivatives, and anti-TGF beta antibodies.

Claim 6. (Canceled)

Claim 7 (Previously Amended). The method of claim 1, wherein the protein is selected from the group consisting of albumin, globulin, alpha-globulin, $alpha_1$-globulin, $alpha_2$-globulin, beta-globulins, gamma-globulin, euglobulin, pseudoglobulin I and II, fibrinogen, $alpha_1$ acid glycoprotein (orosomucoid), $alpha_1$ glycoprotein, $alpha_1$ lipoprotein, ceruloplasmin, $alpha_2$ 19S glycoprotein, $beta_1$ transferring, $beta_1$ lipoprotein, immunoglobulins A, E, G and M, horseradish peroxidase, lactate dehydrogenase, glucose oxidase, myoglobin, lysozyme, protein hormone, growth hormone, insulin and parathyroid hormone.

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Claim 8 (Previously Amended). The method according to claim 1, wherein the assaying for a protein in the urine sample comprises [a method selected from the group consisting of:

(a) assaying for albumin by a conventional method; and

(b)] assaying for native and intact modified albumin.

Claim 9 (Currently Amended). The method according to claim 8, wherein the assaying comprises:

(a) an antibody method, and

(b) a non-antibody method comprising chromatography, electrophoresis or sedimentation of the sample to test for the presence of the native form and the ~~native or~~ intact modified form of albumin.

Claim 10 (Currently Amended). The method of claim 9, wherein the albumin is detected by an antibody or antibodies specific for both ~~unmodified~~ the native and intact modified forms of albumin.

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Claim 11 (Currently Amended). The method according to claim 9, wherein the albumin is detected by an antibody that is specific for the intact modified albumin.

Claim 12 (Original). The method according to claim 9, wherein the albumin is detected by an antibody that is attached to an enzymatic, radioactive, fluorescent or chemiluminescent label, wherein the detecting step comprises radioimmunoassay, immunoradiometric assay, fluorescent immunoassay, enzyme linked immunoassay, or protein A immunoassay.

Claim 13 (Previously Amended). The method according to claim 1, wherein the assaying for a protein in the sample comprises the steps of; and

(i) detecting the native protein amount by conventional antibody assay;

(ii) detecting the native plus intact modified protein by a non-antibody method.

Claim 14 (Currently Amended). The method according to claim 13, wherein the non-antibody method comprises chromatography, electrophoresis or sedimentation of the sample to test for native ~~or~~ and intact modified protein.

Claim 15. (Canceled)

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Claim 16 (Currently Amended). The method according to claim 1, wherein the assaying for a protein in the sample is by a method selected from the group consisting of partition chromatography, adsorption chromatography, paper chromatography, thin-layer chromatography, gas-liquid chromatography, gel chromatography, ion-exchange chromatography, affinity chromatography, ~~or~~ hydrophobic interaction chromatography, moving boundary electrophoresis, zone electrophoresis, ~~or~~ and isoelectric focusing.

Claim 17 (Original). The method according to claim 1, wherein the assaying for a protein in the sample is by hydrophobic interaction chromatography carried out in a high pressure liquid chromatography (HPLC) apparatus.

Claim 18 (Original). The method according to claim 1, wherein the assaying for a protein in the sample is by detecting albumin in the sample with specific albumin dyes.

Claim 19 (Canceled)

Claim 20 (Currently Amended). A method for identifying a treatment agent for renal disease and/or renal complications of a disease, comprising:

(a) administering a candidate therapeutic agent to a patient;

(b) obtaining a series of urine samples from the patient over time; and

(c) assaying for a protein in each of the samples in the series of samples by a non-antibody assay or an antibody assay which measures ~~both~~ native form of the protein and/or intact modified form of the protein, wherein a decreasing amount of the native and/or intact modified form of the protein over time in the urine indicates that the candidate therapeutic agent is a treatment agent for the renal disease and/or the renal complications of a disease.

Claim 21 (Currently Amended). The method of claim 19, wherein assaying for a protein in the samples comprises assaying for ~~a~~ an intact modified form of albumin, wherein decreasing amount of the intact modified form of the albumin over time in the urine indicates that the candidate therapeutic agent is a treatment agent for the renal disease and/or the renal complications of a disease.

Claim 22 (Previously Added). The method according to claim 13 wherein the protein is albumin.

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Claim 23 (Previously Added). The method of claim 20 wherein an antibody assay is used in step (c).

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Claim 24 (New). The method according to claim 1, wherein an early stage of the disease is diagnosed when intact modified albumin is present in the sample in increasing amount over time.